

JAN 20 2004

K033476
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Summary of Safety and Effectiveness

Hoffmann® II Micro™ External Fixation System Line Extension

Proprietary Name:	Hoffmann® II Micro™ External Fixation System
Common Name:	External Fixation Frame Component
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT, 87 LXT & 87 JEC
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	December 5, 2003

Description:

This Special 510(k) submission is intended to address modifications to the predicate Hoffmann® II Micro™ External Fixation System. The subject and predicate Hoffmann® II Micro™ External Fixation Systems are both fabricated from stainless steel components and carbon connecting rods.

Intended Use:

The Hoffmann® II Micro External Fixation System is an intended to be used with the Half Pins or Transfixing Pins of the Hoffmann® External Fixation System and the Components of the Hoffmann® II External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

Substantial Equivalence:

The subject Hoffmann® II Micro™ External Fixation System shares the same intended use, and basic design concepts as that of the currently available Hoffmann® II Micro™ External Fixation System. Mechanical testing demonstrated comparable mechanical properties to the predicate components.



JAN 20 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Vivian Kelly
Regulatory Affairs Specialist
Stryker Howmedica Osteonics, Corp.
59 Route 17 South
Allendale, NJ 07401

Re: K033476

Trade/Device Name: Hoffmann[®] II Micro[™] External Fixation System

Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener, Smooth or threaded metallic bone fixation fastener

Regulatory Class: II

Product Code: KTT, LXT, JEC

Dated: January 6, 2004

Received: January 7, 2004

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

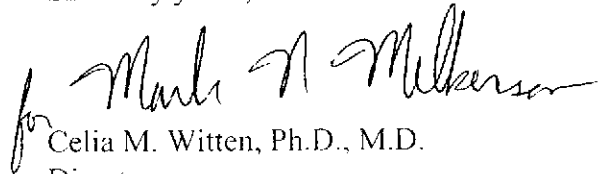
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Ms. Vivian Kelly

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033476

Device Name: Hoffmann® II Micro External Fixation System

Indications For Use:

The Hoffmann® II Micro External Fixation System is an intended to be used with the Half Pins or Transfixing Pins of the Hoffmann® External Fixation System and the Components of the Hoffmann® II External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark A. Milken
Division of General, Restorative
Dental Devices

K033476